EXHIBIT D

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING,
SALES PRACTICES AND PRODUCTS
LIABILITY LITIGATION
_____/

THIS DOCUMENT RELATES TO: MDL Docket No. 1629
Bulger v. Pfizer, et al. Master File No. 04-10981
07-11426-PBS

Smith v. Pfizer, et al.
05-CV-11515-PBS
Crone v. California State Court
_____/

The videotaped deposition of SHEILA WEISS SMITH, PH.D. was held on Monday, December 22, 2008, commencing at 9:17 A.M., at the Law Offices of Goodell, DeVries, Leech & Dann, LLP, 20th Floor Commerce Place, One South Street, Baltimore, Maryland 21202, before Ronda J. Thomas, a Notary Public.

Job No.: 183061
REPORTED BY: Ronda J. Thomas, RPR, CLR

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(APPEARANCES continued on next page.)

(APPEARANCES continued.)

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INDEX

Deposition of SHEILA WEISS SMITH, Ph.D.
December 22, 2008

PROCEEDINGS

(Whereupon, documents were premarked as Deposition Exhibit Number 18, 19, 20 and 21.)

THE VIDEOGRAPHER: We are on the record. The time is 9:17 a.m. My name is Robert Kowalchik of Nationwide Video Production. The date today is December 22, 2008. This deposition is being held in the office of Goodell DeVries located at One South Street, Baltimore, Maryland.

The caption of the case is in Re: Neurontin Marketing Sales Practices and Products Liability Litigation in the United States District Court, District of Massachusetts. MDL Docket No. 1629 Master File No. 04-10981.

This document relates to Bulger v. Pfizer, et al. 07-11426-PBS and Smith v. Pfizer, et al. 05-CV-11515-PBS and cross noticed in the case of Crone v. Pfizer.

The name of the witness is Sheila Weiss Smith. At this time the attorneys will identify themselves and the parties they represent, after which our court reporter, Ronda Thomas of Doerner and Goldberg, will swear in the witness and we can proceed.

MR. ALTMAN: Keith Altman on behalf of Finkelstein & Partners for the Plaintiffs Products

label.
Q You're not a clinician?
MR. BARNES: Are you finished your answer?
A But I think that's where I'm narrowing it to that. So not the whole label. I also did a lot of work in pregnancy registries and the labeling for drugs and pregnancy.
Q Okay. You're not a clinician, correct?
A That is correct.
Q Have you ever written a pharmaceutical label from scratch?
A No, I have not.
Q Have you ever written any portion of a pharmaceutical label?
A No.
Q Have you ever corresponded with the FDA concerning a label?
A What do you mean by corresponded?
Q Have you ever, in any of your work, have you ever been responsible for corresponding with the FDA about the adequacy of the label or whether a label needs to be changed or anything concerning a product label?
MR. BARNES: Does your question concern her work on Pfizer committees as well to correspond --

MR. ALTMAN: No. Outside of that -- outside of the FDA.
MR. BARNES: Outside of your work with the FDA, have you corresponded with the FDA about labeling?
A That hasn't been my position to be the correspondent. I worked and advised the FDA and I've worked for companies that have been working on labeling issues, but I'm on an advisory role, not as a person that would be the contact person.
Q And I think you said your advisory role is limited to epidemiology and pharmacoepidemiology issues?
MR. BARNES: As it relates to label.
Q With respect to labeling?
A As it relates to labeling, some organ risk management. So I'm using the broad drug safety issues.
Q But they would all have in commonality, they would be epidemiologic or pharmacoepidemiologic issues, correct?
A Based on those issues, yes.
Q Have you ever reviewed a label to decide whether the label had a -- was accurate from a clinical perspective?
MR. BARNES: What do you mean by clinical perspective?

Q To a doctor?
A Isn't it all the same thing?
Q No, it's not all the same thing.
MR. BARNES: Objection. Assuming facts not in evidence. Vague.
Q Are you qualified to take a look at a label and decide whether the label accurately represents all of the -- all of the risks known about the product?
MR. BARNES: Objection.
A I'm not sure any one person can know if one label has every single thing in there. Those labels are huge and there's not one person with all the expertise.
Q Have you ever written to the FDA suggesting the labeling change?
A No, I don't typically write to the FDA.
Q Have you ever been part of a group assessing whether a label should be changed?
A Yes, I have.
Q When was that?
A On a number of occasions I have served either on an advisory committee or worked as a consultant to the FDA. On a couple occasions for companies dealing with particular risks and risk management programs. So I've worked on both sides

consulting with them about the risks.
Q Do you know about how many times you've done this? And I don't mean, like, I'm not asking you if a project involved, you know, 20 different interactions. I mean, let's break them up into projects. Do you know about how many projects you worked on in that capacity?
A Probably about a dozen.
Q When you were on the advisory committee, how many of those products involved you being on the FDA advisory committee?
A I probably been on about six or eight advisory committees.
Q When you were on the advisory committee -- were you ever on the advisory committee for the approval of a product?
A Yes, I was.
Q Which products?
A The most recent one, which was before I started on this case, was a -- it was a antiviral drug, it was a Pfizer antiviral drug, Maraviroc.
Q Okay. Before that?
A Before I started any of this.
Q And before that?
A MT100.

psychiatric conditions had an event of suicidal and self-injurious behavior?
A Higher than what?
Q Than the other indications on this chart?
MR. BARNES: The issue here, maybe you can help us, just for the record, when you look up -- all the percentages here do not add up to 100 percent. So it's difficult for -- to answer that question. When you look at it, you only have, like, 25 percent of the -- you add up all these things and you've got much less than --
Q I'll go at it a different way. If you take a look at 2000 June 30, 6/30?
A Okay.
Q This chart shows that 9 percent of the serious reports where the indication was psychiatric conditions with suicidal and self-injurious behavior.
A Were these only among the psychiatric conditions?
Q 9 percent of the people who took it for psychiatric indications, where that was indicated in the database, is for a psychiatric condition. Okay?
A Not yet.
Q All right.
A Not yet.

Q I'm telling you that at 2000, 6/30, June 30, 2000, 9 percent of the serious adverse event reports where the indication was a psychiatric condition contained a term for suicidal and self-injurious behavior. Okay?
A In which the indication was specified as psychiatric.
Q As psychiatric?
A That is what I believe this is telling me.
Q And for antiepileptic at the same time in point it appears to be about 1.6 percent; is that correct?
A Antiepileptic? It's hard to say, but yeah, somewhere about 1 percent maybe.
Q I'm sorry, you're right, a little above 1 percent, correct?
A 1 percent of the serious reports had HL -- one of these HLTs in there.
Q Right.
A Among those who specified an outcome, antiepilepsy.
Q Right.
A Okay.
Q Now if you look at this chart, what it shows is that the percentage for psychiatric conditions

is higher than any of the other conditions, correct?
A Well, because I don't know the N's and --
Q Just the percentage, I'm not asking about N's. The percentage is higher, correct?
A But it could be one out of 2 or 1 out of 10. So it may not be meaningful.
Q But the percentages are higher?
A The percentage are different. I don't know how meaningful they are because I don't have access.
Q But is the percentage higher for psychiatric conditions than the other conditions?
A The percentage is different, yes.
Q Are they higher?
A 9 percent is higher than 1 percent, yes.
Q And at the data point before is it also higher at June 30th of '99?
A Again, I'm not sure about the significance of it. Whether it's statistically significant, the underlying N's. We could be talking about three cases here. But the numbers -- the percentages are different.
Q And, in fact, at every point after 1999 on this chart the psychiatric conditions is higher than the other curves, correct?
A Was this zero over zero or? You have some

zeros here. Zero percentages.
Q No, that means there are no suicidal and self-injurious reports -- no serious for psychiatric conditions at that point in time?
A Thank you.
Q It's zero. It's not zero over zero. It means zero. It's not undefined. It's zero.
Anyway, but at every point after 1999 the percentage for psychiatric conditions is higher, correct, than any of the other indications?
A After 1999?
Q June 30th of '99, that data point. Everything is higher, correct?
A The percentages are higher for that subgroup.
Q Now, is one explanation for that observation that these are people with psychiatric conditions and people with psychiatric conditions tend to commit suicide more than people with these other conditions?
A I would say very strong possibility.
Q That's one possibility?
A That they have a lot of underlying conditions. They may be treated because of that very reason.

Q That's correct.
A High risk.
Q That's what we talk about with confounding indication, correct, confounding by indication; is that correct? That's what you were talking about?
A Yes.
Q Now, is another possible explanation that Neurontin had no efficacy for these people and so basically you were dealing with people who had psychiatric conditions who were not receiving any treatment and they committed suicide?
MR. BARNES: Objection. Assumes facts not in evidence and --
A It's way beyond what I can take from this chart. We don't have anything about efficacy. We don't have anything about whether they're on other treatments. And I would expect a lot of them are on other drugs, from what I've seen.
Q I just asked if one possibility is that Neurontin is not efficacious for these people?
A It's so far beyond what this shows, that's a real big leap.
Q Is it a possibility?
MR. BARNES: If you --
A For everybody? I can't imagine.

Q Is it a possible that that's what's going on, that Neurontin has no efficacy?
MR. BARNES: Objection.
A It's not a reasonable assumption based on this chart.
Q Is it possible that Neurontin actually is causing harm?
MR. BARNES: Objection.
A Based on all of the data that I've seen, there is no evidence at all that Neurontin is causing harm.
Q But you've never looked at the data by indication, correct?
A I looked at the FDA analysis which they looked at the indications for the trial and this is absolutely not what they saw.
Q They did not look at spontaneous data, correct?
A Right, because they don't believe that the spontaneous data has any validity for looking at this outcome because of the confounding indication which is probably what you're seeing here.
Q But that's speculation --
MR. BARNES: Objection.
Q -- that's probably what you've seen,

correct?
A Confounding by indication is the biggest problem we have in pharmacoepidemiology, and it's the first thing one considers when they're looking at spontaneous data or observational data in general. So it's a pretty good guess. This looks pretty clear.
Q Is it also possible that the drug is actually causing people to commit suicide based on this chart?
MR. BARNES: Objection.
A Based on this chart, you can't take that leap.
Q But you can take the leap that it's confounding by indication?
A That is the first explanation that I would consider when I look at this because if it's biological you would expect the rates to be up on all the groups.
Q What?
A You would expect the rates to be elevated on all the groups. Why would you expect --
Q So is it your opinion that drugs affect every population of people the same way. That they don't have different effects depending on a particular population?
A Can you clarify that.

Q Sure. Are some drugs contraindicated to people are who allergic to a substance within the drug?
A They can be.
Q So for that particular population, there is a risk that is different in using the drug than for people who are not allergic to the drug, correct?
A An allergic response, yeah.
Q The risk is different for that population, right?
A The risk of having an allergic response is different. It's not zero in the people that haven't had a previous allergy, but it is lower.
Q But there's a different risk, correct, there's a risk differential?
A Right. Everyone has the risk, but the likelihood may be different.
Q How do you know that people who are bi-polar don't have a different risk in using Neurontin than people who are epileptic?
MR. BARNES: Objection.
A I have no evidence to base that on.
Q But you don't know one way or the other, correct?
MR. BARNES: Objection.
A I know from the literature that there's

MR. ALTMAN: This is a signal.
MR. BARNES: Well, objection. Vague.
A Yeah, within the context, I'm not quite sure what you're talking about.
Q That's fine. Do you agree with spontaneous reporting has been designed as a system for hypothesis generation in the first place. As a rule for the study using the most appropriate and usually different method is needed to put the hypothesis to the test?
A Let's break it up. I agree with the first sentence. What's the second sentence.
Q As a rule further study using the most appropriate and usually different method used is needed to put the hypothesis to the test?
A I agree that if you see an alert, or clinically relevant signal, you need to follow-up with another method to test the hypothesis in almost every case.
Q I think one thing we never finally finished up this morning. And I think I asked you. If you observe an alert, under what conditions is it okay to do nothing with the alert. Can you give me some examples of when it would be okay?
A An alert is purely statistic.
Q Okay. Does an alert need to be evaluated

whether it has clinical significance?
A There are and there should be, within the company and within the FDA, protocol beforehand on how one deals with statistical alerts from data mining and what the triage procedure would be.
Q Understood. Does there have to be some triage procedure?
MR. BARNES: At what time? As of today's standards? As of today or different times? You're talking about a period of time here that is long. So if it's as presently defined or as understood in 2001. I mean, it's a completely vague as to time.
MR. ALTMAN: I'm asking her opinion on that.
Q Whether an alert needs to be followed up? Does something need to be done with an alert or is it okay to simply ignore it?
MR. BARNES: Objection. She's testified that you don't even have to do -- you're not even required to do anything with an alert under your own premise.
MR. ALTMAN: You're messing up the question.
Q If you see an alert, is it acceptable to do nothing?

A In what context?
Q To do simply nothing. You observe an alert. You run some kind of data mining analysis, you come up with an alert as we have discussed.
A For me or you?
Q I'm not asking for me or you. A company --
A A company.
Q -- defines an alert.
A For their drug?
Q For their drug. Is it okay to do simply nothing?
A I don't know what their SOPs are or their legal requirements. Is the alert evaluated clinically immediately? Is it separate? So, I mean, it really would depend on what's going on.
Q Does some kind of evaluation need to take place on the alert to decide whether to go further?
A I believe that it needs some clinical evaluation to see if the alert is actually a signal or if it is something that uninterpretable or something that may not be relevant.
Q Okay. So something has to happen. You see an alert. You got to do something. You may conclude that it's not relevant, you may conclude it's uninterpretable, you may do something. But what's not

okay is run your data mining and simply put your stuff on the shelf --
MR. BARNES: If you have an opinion.
A I can't make an opinion like that because you're talking in general and things are evolving even as we speak on how data mining is best used.
So things are evolving now and that's a good question that I don't think we have been able to answer yet as an industry on how to deal with data mining.
Q For your -- when you access Q Scan, is that through a web site? Do you go into your log-in and you can run your analyses?
A That's correct.
Q And you can download some of that data or computations or whatever that it produces?
A It's an application. It has software on it to do statistics, that's all it is.
Q How is the output given to you?
A It depends on what you're looking at.
Q The first time you provided us some Excel spreadsheets of data that formed part of the basis of your report, do you recall that?
A I believe I gave you the raw counts that were used to calculate the PRRs, yes.

Q Did you generate charts similar to that when you did your analyses in your supplemental report?
A Did I for here? No.
Q For your supplemental report?
A No, I didn't. Raw data.
Q How did you actually -- the charts that are in your supplemental report, did those come straight from Q Scan or do you actually have to make those charts? I'm talking about ones on the PRR?
A Which -- give me an example, which one?
Q Your supplemental report. Let's take on page 22?
A Figure 1?
Q Figure 1, yes.
A So I get the statistic, the PRR statistic, and I put it in an Excel spreadsheet and I plotted it in Excel.
Q I mean, did you hand write that stuff from Q Scan or did you download a chart or something?
A I believe I downloaded a delimited file to a data file.
Q Do you still have those files?
A Probably not. They're raw files. I would just recalculate it.
Q Okay. Did you write out a formal protocol

when you did these analyses?
A I put the protocol in my report. So yes, I decided beforehand what I was going to do.
Q Do you know whether Dr. Blume did a similar thing before she had analyses run?
A Based on the number of tables and runs that you did that were available on the CD that I reviewed, I suspect not.
Q Do you know if Dr. Blume said to run all adverse event terms at all MedDra levels?
A That's what it looks like to me that was done.
Q Is there something wrong with doing that, running all adverse event terms on all MedDra levels?
A Depends on what context.
Q Well, in this context here you make the suggestion that -- frankly, I think you make the suggestion that there's something wrong with doing that.
If the practice is to run every single adverse event term that actually occurs at all four MedDra levels, is there something fundamentally wrong with doing every possible term and generating those data?
A But what you -- you can look at whatever

you want to look at. But what is the intent and if you're going to do statistical analysis, you have to predefine what is your threshold.
I don't think it's a legitimate exercise to do the analysis and then afterwards to say, okay, here's my cut off. I like this cut off because this gives me what I want. You have to define your cut off threshold, algorithm statistic ahead of time.
Q Do you know whether Dr. Blume did that or not?
A She mentioned nothing about any statistic, any threshold, any significance level. I saw nothing in any report.
Q But that doesn't mean that she didn't do that, correct?
MR. BARNES: Objection.
A If I saw nothing in all the pages of all of these reports that she put together, she didn't bother to mention that and she mentioned everything else, I would assume that she didn't do it.
Q Did you put your thresholds in here?
A Yes, I did.
Q Where are they? Is that what you used on page 21?
MR. BARNES: Take your time. Maybe in your

first report.
A That's what I'm looking at.
Q I'm looking at page 21 of your supplemental report.
A I'm looking at page 21 of my first report using the full data set as a background, I calculated accumulated series of proportional reporting rates with a threshold PRR of greater than 2 with a chi-squared greater than equal to 2 commonly cited --
THE COURT REPORTER: Say that again.
THE WITNESS: Can I just reference you where it is?
THE COURT REPORTER: Whatever you'd like.
THE WITNESS: This is the first report. Do you know what it's labeled?
MR. BARNES: I don't think he marked it an exhibit.
THE WITNESS: Okay. I apologize. In my original report on page 21 I state the criteria that I used to do my analysis. The threshold that I used.
BY MR. ALTMAN:
Q If somebody decides to monitor specific adverse event information going forward for some reason, is that still data -- would you still consider that to be data mining?

A It depends on how they're monitoring it.
Q If I want to -- if I decide that I'm concerned about a particular adverse event based on for whatever reason. I've done some review. I've made clinical judgment that these particular adverse events are of concern to me, and I want to monitor those going forward and see what I see. Do you still consider that to be data mining in terms of looking at particular adverse events going forward?
A Not necessarily.
Q So that's more of a data -- can we call that a data -- can we call that monitoring, I mean simply a directed monitoring?
A It's some form of post-marketing surveillance.
Q Do you have any opinion whether there was any information in the possession of the company in 1994 that said it should have suggested to the company that they should perform any kind of enhanced monitoring of any particular adverse events associated with the use of Neurontin?
A Based on my review of the clinical trials that they submit to the FDA and the epidemiological literature and the spontaneous reports, I don't see that at all.

Q I'm talking about in 1994 when the drug was first put on the market. You wouldn't have had spontaneous reports and you wouldn't have had epidemiologic data?
MR. BARNES: Objection. Asked and answered.
A Based on all the information I reviewed, even today, I do not see any signal, any signal of disproportional reporting, any statistical associations, even today. So I cannot imagine that there would be anything available into 1994 if there's nothing available even to this point after it's been used so extensively.
Q Once again, your opinion is limited to not involving somebody's clinical judgment that there is something that should be monitored, correct?
MR. BARNES: Objection. She stated several times what she's based her opinion on, so state it again.
A I relied on the clinical judgment of the experts that put together the reports, the Parson's report, the FDA analysis which had a number of clinical experts on it, the medical literature which has clinical experts writing paper.
So based on the preponderance of evidence

that I reviewed, the epidemiological literature and the clinical literature, I do not see any information even today that would make one believe or even suggest that there would be a statistical association with Neurontin and suicidality.
Q Just quickly, I have these invoices here. I'll mark these. This is the only copy. I guess we'll just mark it as an exhibit. I just want you to review this and see if these appear to be your invoices in this case?
MR. BARNES: Up through today or?
MR. ALTMAN: Up to today. I mean, those are the invoices I was handed. I have no basis of knowing anything else.
A These are the invoices from the last -- the deposition, the last deposition. It's not prior to that. Except for this one because they didn't pay until afterwards. So this is things received in 2008.
Q Let's mark that as the next exhibit.
(Whereupon, a document was marked as Deposition Exhibit Number 28.)
Q I guess we'll mark as -- these are the disks that you brought with you today?
A Yes, I brought those with me today.
Q Why don't we mark these as 29 through 32.

And I believe we are out of time much to your chagrin. I thank you for your time and I just want to put on the record that, once again, I did not have the opportunity to access Q Scan data. I don't know what that access would do in terms of my desire to ask questions of this witness and so under the MDL we're entitled to two days and under the California rules there's no time limit. And therefore I'll hold this deposition or I'll adjourn this deposition for now pending my review of that information which may require some further examination of this witness.
MR. BARNES: Okay. Well, I think what I would ask you to do is put your request -- precise request to us in writing and we will respond as to the Q Scan data, what your current request is and we'll are consider it and go from there.
MR. ALTMAN: That's good.
EXAMINATION BY MR. BARNES:
Q One question of the witness before we conclude. Very early in the deposition Mr. Altman asked you a question regarding the scientific rigor in which you prepared your report and you stated that you used the same, I'll paraphrase, it, the same scientific rigor that you would use in doing your other professional work except you didn't have as many hands

to look at the references, what did that mean?
A It means that this did not go through a formal peer review process. So if I write a paper, one, I'll have usually many co-authors. So everyone gets to review that and then I have a -- an editor in-house that will go through and edit. And then when I submit it to a journal for publication, it gets sent out to at least two, three, four peers that go through every aspect of the paper.
Q In that process from time to time do they find typos and errors within the draft manuscript?
A No matter how many times you write and rewrite it, there's always something, yes. They are noticed. Then also if it's accepted the journal has editorial staff that again go through it and sometimes you'll find them.
Q So that's the difference?
A And then proofs. There's many, many steps in the process to make sure.
Q So the error that Mr. Altman pointed out this afternoon is something that would perhaps come to light during the normal peer review and editing process that you do in your normal scientific and research activities, correct?
A Absolutely. Very minor typos or things

like that would be caught and corrected. Absolutely.
MR. BARNES: Thank you. No further questions.
EXAMINATION BY MR. ALTMAN:
Q I have to ask a brief follow-up. You don't know how many errors there are in either your supplemental report or your original report if you didn't go through that process, correct?
A I went and did this as thoroughly and as carefully as I could. I found errors in everybody's reports on this case, including a couple of typos on my own report.
Q But you don't know if there are other errors in your report, correct?
A I know there's a couple of typos.
Q I'm not talking typos, numerical errors?
MR. BARNES: She said that was a typo.
A I know there's some typos in it.
Q Is that --
A But, I mean, I am going to assume that there are not unless I find something. I've gone through and worked this very hard to make sure that this is accurate and correct.
Q Okay.
MR. BARNES: No further questions. Thank

you. We will read and sign.
(Whereupon, CD's were marked as Deposition Exhibit Numbers 29 through 32.)
(Deposition concluded at 6:30 p.m.)

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

_____
SHEILA WEISS SMITH, Ph.D.